

**MEDICAL LABORATORY BOARD  
MINUTES**

**Date:** January 12, 2006

**Time:** 9:00 a.m., CST

**Location:** Cumberland Room  
Ground Floor, Cordell Hull Building  
425 Fifth Avenue North  
Nashville, TN 37247

**Members Present:** Linda Lahr, MT Chairman  
Jere Ferguson, MD, Vice-Chairman  
Dennis Carter, MD  
Edward McDonald, MD  
John C. Neff, MD  
Yvonne Davis, Medical Technologist  
Martha Duncan, Medical Technologist  
Alison McDonald-Spakes, Cytotechnologist  
Delores Voigt, MT Hospital Administrator

**Members Absent:** Thomasa Cooper, Medical Technologist  
Norman Crowe, Independent Laboratory Manager/Representative  
Kelly S. Terry, MT

**Staff Present:** Lynda S. England, Medical Technologist, Director  
Cheryl H. Thacker, Medical Technologist, Consultant  
Robert Kraemer, Jr., Advisory Attorney  
Julia Daniels, Medical Technologist Consultant/ Surveyor  
East Tennessee Regional Office  
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,  
East Tennessee Regional Office  
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,  
Middle Tennessee Regional Office  
Irmgard Brown, Medical Technologist Consultant/Surveyor,  
Middle Tennessee Regional Office  
Mary Hamblen, Medical Technologist Consultant/Surveyor  
West Tennessee Regional Office  
Jerry Kosten, Rules Manager

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**Staff Absent:** Robbie Bell, Director-Health Related Boards, Ex-Officio Board Member  
Karon Daniels, Medical Technologist Consultant/ Surveyor,  
West Tennessee Regional Office

**Quorum:** A sufficient number of board members were present to constitute a quorum.

**Presiding Officer:** The meeting was called to order by the Board Chairman, Linda Lahr at 9:10 a.m.

Board Members introduced themselves to the audience.

**Welcome:** Ms. Lahr welcomed the guests and visitors to the board meeting.

**Election of Vice-Chair:** Dr. Neff nominated Dr. Jere Ferguson for the vice-chair of the Medical Laboratory Board for the year 2006. Dr McDonald seconded the nomination. The vote for approval from members was unanimous.

**Introduction of CLIA Manager:** Ms. Irmgard Brown was introduced as the new CLIA manager for Tennessee. Ms. Brown was formerly one of the Middle Tennessee Regional surveyors. Ms. Brown will be attending Board meetings when her schedule permits.

**Board Minutes:** A motion to approve the July 13, 2005 Personnel & Education Committee minutes was made by Dr. McDonald.  
Second: Mr. Crowe  
These minutes were approved.

A motion to approve the minutes of the full Board from the July 14, 2005 meeting was made by Dr. Ferguson.  
Second: Dr. Carter  
The minutes were approved.

**Board Report-Personnel & Education Committee:**

Ms. Duncan presented a report of the actions of the Personnel & Education Committee meeting held on January 11, 2006.

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Motion to accept this report: Dr. McDonald

Second: Dr. Neff

The report was approved.

**Contested Cases:** There were no contested cases presented during this meeting.

**Board Report-Tennessee Professional Peer Assistance Program:**

Mike Harkreader, MA, RN

TNPAP State Director

Mr. Harkreader gave the following report to the board:

Statistics for the period July 1, 2005 to December 26, 2005 stated there were nine (9) referrals with two (2) individuals in monitoring status and three (3) individuals in the evaluation status.

One (1) individual refused to participate in the program and was reported to TDOH and four (4) individuals were found to not need monitoring.

The reason for the referrals to TNPAP indicated a history of arrest and a history of substance abuse. All nine (9) referrals were from the Board's administrative office.

TNPAP can take referrals on anyone with mental health issues and boundary violations (sexual boundaries, anger management, etc.) Individuals with major depression, PTSD or anxiety disorders may also be referred to TNPAP per Mr. Harkreader.

Motion to accept this report: Dr. Ferguson

Second: Dr. Carter

Approved.

A copy of Mr. Harkreader's report is on file in the board's administrative office.

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## **Board Report-Rules:**

Jerry Kosten-Rules Manager

### *A. Rules Amendments:*

Mr. Kosten reported on a rulemaking hearing held December 15, 2005 concerning the following amendments to:

#### 1-Rule 1200-6-1-.12 Referral of Cultures to the Department of Health

- a. Shiga-like toxin producing *Escherichia coli* non-0157(STEC).
- b. Shiga-like toxin positive stools and/or EIA positive broth shiga-like toxin.
- c. Change *Escherichia coli* 0157: H-17 to *Escherichia coli* 0157.

#### 2-Rule 1200-6-3.16 Alternate Site Testing-Board Appearance

There were no comments during the rulemaking hearing to these proposed rule changes.

A motion to adopt these amendments was made by Ms. Duncan.

Second: Dr. Neff.

A roll call vote was taken with all members present voting aye.

### *B. Authorize Rulemaking Hearing:*

The board authorized a rulemaking hearing to be held March 17, 2006 for:

#### 1-Rule 1200-6-1-.01 Definition-Special Analyst, Level II –Chemical Terrorism.

#### 2- Rule 1200-6-1-.21 Qualifications and Duties of the Medical Laboratory Supervisor.

#### 3-Rule 1200-6-1-.22 Qualifications, Responsibilities and Duties of Testing Personnel.

#### 4-Rule 1200-6-3-.02 Licensing Procedures.

#### 5-Rule 1200-6-3-.03 Change in Location, Director, Owner, Supervisor or Testing in a Medical Laboratory.

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6-Rule 1200-6-3-.16 Alternate Site Testing-Physician's Office  
Laboratories.

A motion to authorize a rulemaking hearing was made by Dr. Ferguson.  
Second: Dr. McDonald.  
Approved.

**Ratifications:**

The following items were presented to the Board for ratification per staff,  
state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed  
facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

**Board Director's Report/Discussion:**

Lynda S. England BS MT(ASCP)  
Director

Ms. England reported quarterly administrative office/staff activities to the  
Board members. This report included administrative office statistics,  
referrals from this office for TNPAP for peer assistance services and  
website update information.

Motion: Dr. McDonald  
Second: Dr. Carter  
Report Approved.

The complete director's report is filed in the administrative office.

**Direct More Than Three (3) Labs**

**Rule 1200-6-3-.13(5) Medical Lab Facilities:**

There were no requests made to the Board during this meeting.

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**Reinstatement of License:** There were no requests for licenses to be reinstated during this meeting.

**Reports/Discussion:**

**Reports:**

Regional Consultant/Surveyor – Proficiency Testing (PT) &  
Complaint Investigations/Licensed Laboratory Facilities

**East Tennessee Regional Office**-Julia Daniels, Consultant II/Surveyor;  
Onezean Otey, Jr., Consultant I/Surveyor

Mr. Otey gave the report:

*Unsatisfactory/ Unsuccessful Proficiency Testing:*

The East Tennessee Regional Office reported three (3) facilities with a first occurrence of unsuccessful participation in proficiency testing events.

Facility #1 Unsuccessful PT Analyte C3 and C4

Specimens were tested out of sequence; mislabeled

Facility #2 Unsuccessful PT Bacteriology

Anaerobe-Failure to follow CAP incubation instructions

Rubella-waiting on plan of correction

PTT-Clerical Errors in transposition of data, employee counseled.

ASO-calibration omission; controls were in upper range of limits

No patients were determined to be negatively impacted.

Each facility responded with an acceptable plan of correction (waiting on POC on Rubella) to include technical assistance and testing personnel competency verifications. No patient results were affected during these events.

*Complaint Investigations:* The East Tennessee Regional Office conducted zero (0) investigation(s) during the last quarter of 2005.

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**Middle Tennessee Regional Office**- Sandra S. Bogard,  
Consultant II

Ms. Bogard gave the report:

*Unacceptable/Unsuccessful Proficiency Testing:*

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) was zero (0).

*Complaint Investigations:*

The Middle Tennessee Regional Office has conducted zero (0) complaint investigation(s) during this quarter.

**West Tennessee Regional Office**-Mary J. Hamblen, Consultant II/Surveyor; Karen Daniels, Consultant I/Surveyor

Ms. Daniels gave the report:

*Unacceptable/Unsuccessful Proficiency Testing:*

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): Zero (0).

*Complaint Investigations:*

There were zero (0) complaint investigations from the West Tennessee Regional Office this quarter.

Motion to accept these regional reports: Dr. Ferguson.  
Second: Dr. Carter.  
Report Approved.

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**Reports/Discussion:**

**Health Related Board's Report/Discussion:**

Robbie Bell, Director

Ms. Bell did not give a report during the board meeting.

**Office of General Counsel Report:**

Robert J. Kraemer, Jr.

Advisory Attorney

Mr. Kraemer led the discussion of the following items:

**Criminal Background Checks & Screenings (05-1026)**-The rulemaking hearing was held on March 24, 2005 and these amendments were adopted by the Board on April 14, 2005. They were sent to the Attorney General on April 19, 2005 and they are still there.

**Director, Delegation, Reportable Cultures and POC (05-1170)**-The rulemaking hearing was held on July 8, 2005 and these amendments were adopted by the Board on July 14, 2005. They were sent to the Attorney General on July 21, 2005 and are still there.

**2005 Legislation Amendments (05-1327)**-The rulemaking hearing was held on September 26, 2005, with the amendments adopted by the Board on October 13, 2005. They were sent to the Attorney General on October 18, 2005 and are still there.

**Alternative Site Testing** and Reportable Cultures (05-1549)-The rulemaking hearing was held on December 16, 2005 and after response to comments, these amendments are ready for adoption at this meeting.

**Litigation:**

The Office of General Counsel currently has zero (0) open disciplinary cases pertaining to the Medical Laboratory Board.

**Topics for Discussion:** None.

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Motion to Accept Report: Dr. Neff

Second: Dr. Carter

Report Approved.



**Bureau of Investigations (BIV) Report:**

Mr. Kraemer gave this report from information provided by the Bureau of Investigation which included five (5) older complaints from the previous years in that department.

Currently per Mr. Kraemer's report there are zero (0) complaints in BIV for review.

Motion to Accept Report: Dr. McDonald.

Second: Dr. Neff.

Report Approved.

**Office of Health Licensure & Regulation:**

Judy Eads, RN

Assistant Commissioner of Health

No report was given by Ms. Eads during this meeting.

**Financial Report:**

Lisa Tittle

Fiscal Officer

A copy of the financial report for the fiscal year 2005-2006 was mailed to each board member earlier in the month. A copy of this report is included in each member's board book and also on file in the administrative office.

**Waived Testing Procedures:**

There were no additions or deletions made to the waive test lists.

**Point of Care Task Force:**

There was no report made by the task force during this meeting.

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**Review Eligibility of Medical Laboratory Director:**

1-Safedin H. Beqaj, Ph.D. Pathology

Brentwood, TN 37027

Director: Molecular Diagnostics

Dr. Beqaj requested the Board review his application for licensure as a director in molecular diagnostics. Dr. Beqaj took his American Board of Bioanalysis (ABB) examination in general knowledge and molecular diagnostics on November 9, 2005.

On December 8, 2005, Dr. Beqaj was informed by ABB that he was unsuccessful in obtaining a passing score for both examinations. Dr. Beqaj submitted a letter commenting on the molecular diagnostics portion of the examination which he felt did not reflect ABB's examination-study guide.

Dr. Beqaj requested the Board extend the date of his temporary license until he could challenge the next available examination which is scheduled for June 8, 2006.

Documentation from ABB submitted to the administrative office on January 12, 2006 revealed ABB's intent to have the original examination score stand. The content of the letter (January 12, 2006), does not make Dr. Beqaj eligible for an extension of his temporary license. As of December 8, 2005 the temporary license is void for failure to pass the examination.

2-Oristyne E. Walker, Ph.D.  
Jackson, TN 37-8301  
Director-Microbiology

Dr. Walker was previously licensed as a Director in Immunology (04/15/05) and wishes to add the modifier of director in Microbiology.

Motion: Dr. McDonald  
Second: Dr. Neff  
Approved.

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3-Abdel-Baset M. Halim, Ph.D.  
Arden, NC 38704

Dr. Halim was previously licensed a Director in Clinical Chemistry (01-31-00) and wishes to add the modifier of Director in Molecular

Diagnostics. Dr. Halim completed the American Board of Clinical Chemistry examination in Molecular Diagnostics on March 25, 2005.

Motion: Dr. McDonald  
Second: Ms. David  
Approved.

4-Gary A. Kitos, Ph.D.  
Franklin, TN 37067

Dr. Kitos requested licensure as a Director in the specialties of Clinical Chemistry and also Immunology after completion of the American Board of Bioanalysis examinations.

Motion: Dr. McDonald  
Second: Ms. Davis  
Approved.

**Other Business:**

1-“Factual Situation-#1” The Board discussed personnel qualifications for those individuals responsible for providing laboratory testing procedures to those patients that have met “brain death” criteria and may qualify for organ donation. Because these laboratory tests would assure that all metabolic processes would be maintained for continued viability, accountability is mandatory. If these tests are not being performed in a licensed clinical laboratory, then an exemption for point of care testing (POCT) must be granted by the Board. A motion to deny these testing procedures to a non licensed entity was made by Dr. Ferguson with a second to the motion by Dr. McDonald. The motion carried.

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2- The Board discussed creating a new medical laboratory professional licensure category. This category would encompass those individuals work in the Tennessee Department of Health, Laboratory Services, Hart Lane, Nashville, TN in a Level II Focus Area D laboratory for chemical terrorism.

Note: Please see the Personnel & Education Minutes,  
January 11, 2006 for complete information.

**Statement of Next Meeting:**

The next meeting will be held on April 13, 2006 beginning at 9 am, CDT in the Cumberland Room, Ground Floor Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

**Record of Adjournment:**

The meeting adjourned at 12:10 pm CST on a motion properly filed by Ms. Duncan.

Second: Dr. Carter.

Approved.

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Linda Lahr, MT  
Chairman, Tennessee Medical Laboratory Board

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Date

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Point of Care Exemption Requests  
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**REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES**

1. **Cookeville Regional Medical Center**  
**142 West Fifth Street**

**Cookeville, TN 38501**

Facility Representative: Marilyn C. Key, MT (ASCP)  
Administrative Laboratory Director

This facility request was for Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) to perform and report Cardiac Marker Testing procedures (Troponin I, CKMB, Myoglobin and BNP) in the Emergency Room using the Biosite Triage Cardiac Panel Testing System.

Motion: Dr. McDonald  
Second: Dr. Neff  
Approved.

2. **Methodist LeBonheur Healthcare-South**  
**1300 Wesley Drive**  
**Memphis, TN 38116-6426**

Facility Representative: Nefitite H. Phelps, MSA, MT (ASCP)

This facility request was for Registered Nurses (RN's) to perform and report BNP, Troponin, Myoglobin and CKMB in the Emergency Department utilizing the Triage Metering Plus System.

Motion: Dr. McDonald  
Second: Ms. Voigt  
Approved.

Ms. Davis recused herself from the discussion and vote.

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3. **Gateway Medical Center**  
**1771 Madison Street**  
**PO Box 3160**  
**Clarksville, TN 37043-3160**

Facility Representative: Mary Bowles, MT, ASCP, BSN, RN

Ancillary Testing Manager

This request was for Certified Cardiovascular Perfusionists in the Cardiac Operating Room to perform and report Heparin Assay, Heparin Dose Response, activated clotting times (ACT's), Calculation of Heparin Administration and Calculation of Protamine Dose on the Hepcon HMS Analyzer.

Motion: Dr. Ferguson

Second: Dr. Neff

Approved.

4. Centennial Medical Center  
2300 Patterson Street  
Nashville, TN 37203

Facility Representative: Mollie Wynn, MT (AMT)

POC Coordinator

This facility requested the Board approve the following exemptions:

1-Registered Nurses (RN's), Licensed Practical Nurses (LPN's) and Perfusionists to perform and report blood gases, electrolytes, glucose, ionized calcium, hemoglobin, hematocrit and activated clotting times (ACT's) in the Campus Operating Rooms utilizing the i-STAT instrument.

Motion: Dr. McDonald

Second: Dr. Neff

Approved.

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2-Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) to perform and report blood gases, electrolytes, glucose, ionized calcium, hemoglobin, hematocrit and activated clotting times (ACT's) in the Intensive Care Units utilizing the i-STAT instrument.

Motion: Dr. McDonald

Second: Dr. Neff

Approved.

3-Registered Nurses (RN's), Licensed Practical Nurses (LPN's), Perfusionists and Licensed Radiology Techs to perform and report oxygen saturations and activated clotting times (ACT's) in The Cardiac Cath Laboratory utilizing the i-STAT instrument.

Motion: Dr. McDonald

Second: Dr. Neff

Approved.

Ms. Duncan recused herself from the discussion and vote.

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Attachment 2

Initial Facility Licenses

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**INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION:**

1-Southeastern Pathology Associates

2115 Chapman Road Suite 115-B

Chattanooga, TN 37421

Medical Laboratory Director: Xiao C. Mu, M.D., Ph.D.

Anatomic/Clinical Pathology

Dermatopathology

Specialties: Histopathology, Oral Pathology, Cytopathology

Surveyor: Onezean Otey, Consultant I  
East TN Regional Office

Motion: Dr. Ferguson  
Second: Dr. McDonald  
Approved.

2-Center for Women's Health

1919 Charlotte Avenue  
Nashville, TN 37203

Medical Laboratory Director: Valerie Montgomery Rice, M.D.  
American Board of Reproductive Endocrinology  
Physician: OB/GYN

Specialty: Andrology

Surveyor: Sandra S. Bogard, Consultant II  
Middle TN Regional Office

Motion: Dr. Ferguson  
Second: Ms. Voigt  
Approved.

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3-Endocrinology & Andrology Core Laboratory

Meharry Medical College  
Dept. OB/GYN  
1005 Dr. D.B. Todd, Jr., Blvd.  
4<sup>th</sup> Floor Old Hospital Building, G401  
Nashville, TN 37208

Medical Laboratory Director: Valerie Montgomery Rice, M.D.  
American Board of Reproductive Endocrinology



Physician: OB/GYN

Specialty: Andrology & Endocrinology

Surveyor: Sandra S. Bogard, Consultant II  
Middle TN Regional Office

Motion: Dr. Ferguson

Second: Ms. Viogt